REMARKS

The Office Action of August 24, 2005, has been received and reviewed. Claims 1-17 and 24-40 are currently pending in the application. Claims 1-9 and 36-40 stand rejected. Applicants propose to amend claims 1-4, 6-9, 36 and 39 herein. Claims 5, 10-17, 24-35, 37 and 38 are cancelled herein. No new matter has been added. Reconsideration of the application is respectfully requested.

Claim Rejections—35 U.S.C. § 112, first paragraph

Claims 1-9 and 36-40 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement and as assertedly failing to comply with the enablement requirement. Claims 5, 37 and 38 have been cancelled herein thus mooting the rejection of those claims. Applicants respectfully traverse the remaining rejections as hereinafter set forth.

Written Description Rejections

The Office Action asserted that the claims encompass a genus of indeterminate size, but which could easily encompass millions of different QTLs, including QTLs which are structurally and functionally unrelated to each other and QTLs which have yet to be identified. (Office Action, page 3). However, applicants respectfully submit that the specification provides adequate written description and evidence of possession of the instant claims.

The applicants note that the Examiner acknowledges that there is sufficient written description for "the paternally imprinted QTL comprising the IGF-2 [insulin-like growth factor-2] gene and a marker characterized as nt241(G-A) or as Swc9, wherein the QTL is associated with fat deposit in pigs." (Office Action, page 5).

Amended independent claims 1 and 39 recite, in part, a method for selecting an animal having a parentally imprinted QTL associated with muscle mass and/or fat deposition in the animal.

Independent claims 1 and 39 do not encompass millions of different QTLs or QTLs that are structurally and functionally unrelated to each other. Parentally imprinted QTLs in animals associated with muscle mass and/or fat deposition are likely to be functionally and structurally

related as to the genetic linkages of the responsible genes and the causal gene products for such a trait.

Moreover, possession of the claimed invention may be shown by describing the all the elements of claimed invention by using descriptive words, structures, figures, diagrams and formulas. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572, 19 USPQ2d 1961, 1966 (Fed. Cir. 1997). Applicants respectfully submit that the elements of the claimed invention are described in such descriptive terms as to reasonably convey to one of skill in the art that the inventor had possession of the invention at the time of filing.

More particularly, for independent claims 1 and 39, the specification provides substantial direction for identification of a parentally imprinted QTL in an animal as well as for isolating and defining the genetic markers in linkage disequilibrium with such a QTL. (Specification, Example 1, paragraphs [0053]-[0066]). Thus, one of ordinary skill in the art would conclude that the inventors were in possession of instant invention.

With further regard to amended claim 2 and claim 40, the written description indicates "[t]he invention provides testing such a sample for the presence of [a] nucleic acid wherein a QTL or allele associated therewith is associated with the phenomenon of parental imprinting." (*Id.* at paragraphs [0010] and [0026]; Example 1, paragraph [0060])).

Regarding amended claim 4, the specification describes "[i]n pigs, said cluster is mapped at around position 2p1.7 of chromosome 2" such that one of ordinary skill in the art would conclude that the inventors were in possession of the invention of claim 4. (*Id.* at paragraph [0030]).

Written description for amended claim 6 may be found in the specification which indicates that the "QTL is related to the potential muscle mass and/or fat deposition ... wherein said QTL comprises at least a part of an insulin-like growth factor-2." (*Id.* at paragraph [0030]).

Amended claim 7 is supported by the specification which indicates that "a nt241 (G-A) transversion [is] in the second exon of the porcine IGFII gene and SW9." (*Id.* at paragraph [0041]).

Written description for claim 8 exists by the passage in the specification stating that the "parentally imprinted quantitative train locus (QTL) or fragment thereof capable of being predominantly expressed by one parental allele." (*Id.* at paragraph [0045]).

Amended claim 9 is supported in the passage of the specification that indicates "recombinant alleles linked with meat quality traits such as intra-muscular fat or muscle mass could be fixed in the dam lines." (*Id.* at paragraph [0051]).

Amended claim 36 is supported by the specification reciting "at least a part of the nucleic acid genome of an animal where genetic information capable of influencing said quantitative trait (in said animal or in its offspring) is located." (*Id.* at paragraph [0004]).

Therefore, the specification provides adequate written description and evidence of possession of the instant claims. Reconsideration and withdrawal of the written description rejections of claims 1-9 and 36, 39 and 40 is respectfully requested.

Enablement Rejections

The Office Action alleges that the specification does not reasonably provide enablement for the full breadth of claims 1-9 and 36-40. However, the Examiner has acknowledged that the specification provides an enabling disclosure for identifying a pig having a paternally imprinted QTL wherein the method comprises identifying the presence of the IGF-2 gene having the nt241(G-A) polymorphism in the genome of the pig (*i.e.*, the 2pl.7 QTL) wherein the presence of the QTL is correlated with decreased fat deposit in the pig. (Office Action, page 5).

While applicants respectfully appreciate the Examiner's acknowledgement of enablement, and have presented claims according the Examiner's suggestions, specifically claims 41-45, applicants do not wish to limit the claimed invention to just the use of the markers nt241(G-A) or Swc9. For the following reasons, applicants submit that the specification provides enablement for the full scope of the instant claims.

To satisfy the enablement requirement, a specification must teach those skilled in the art how to make and use the scope of the claimed invention without undue experimentation. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Furthermore, prophetic examples are permitted in patent applications (M.P.E.P., § 608.01(p)(II)) and the use of prophetic examples may make a patent enabling. *Atlas Powder Co. v. E.I. DuPont di Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

When determining undue experimentation, the PTO and the courts look to the factors outlined in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The factors include 1) the quantity

of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

In *In re Wands*, the United States Court of Appeals, Federal Circuit ("CAFC") reversed a rejection for lack of enablement for an application claiming monoclonal hybridomas which secrete specific antibodies. *Id.* at 740. The CAFC found the disclosure of the Wands' patent enabling because there was a high level of skill in the monoclonal antibody art and, despite the relative unpredictable nature of the technology, the patent disclosure provided guidance and real working examples of the invention. *Id.* at 738.

The CAFC reasoned that the specification contained considerable direction and guidance on how to practice the claimed invention, presented working examples, that all the methods needed to practice the invention were well known and that there was a high level of skill in the art at the time the application was filed. *Id.* at 737. Furthermore, the CAFC stated that a considerable amount of experimentation is permissible if it is reasonable with regards to the nature of the art or if the specification provides a reasonable amount of guidance. *Id.*

Following the analysis from *In re Wands*, the specification of the instant specification allows one of skill in the art to make and use the invention commensurate with scope of the claims without undue experimentation. The specification discloses detailed directions and guidance for the full scope of the claims, the referenced methods are well known by those of skill in the art, working examples are disclosed using genetic markers to identify paternally imprinted QTLs in an animal, and the level of skill in the art was high at the time of filing.

More particularly, an example of a parentally imprinted QTL was located on chromosome 2 in the pig and its location was characterized by a number of otherwise arbitrary genetic markers. (Specification, paragraph [0026]; Example 1, paragraph [0060]). In this example, microsatellite markers Swr2516, Swc9, S22623 and Swr783 were used to define a parentally imprinted QTL in the pig, although one of skill in the art would also know that microsatellite, AFLP, RFLP, SNPs or other markers such as SCAR markers might also have been used without undue experimentation. Furthermore, those of skill in the art may also use such markers to identify and characterize parentally imprinted QTLs in any appropriate animal.

In general, for any animal and phenotype of interest, a QTL may span a region of several million bases in the genome as detected through the observed correlation between the presence of a string of contiguous genomic markers and the presence of a particular phenotypic trait. As such, QTL markers allow those of skill in the art to select those animals that have the genetic potential for exhibiting a particular phenotypic trait. Accordingly, the present specification allows those of skill in the art to identify animals with parentally imprinted QTLs associated with the desired phenotype of muscle mass and/or fat deposition.

Additionally, those of skill in the art know that the contiguous genomic markers that indicate the location of a specific QTL in the genome may be many in number. The location of a QTL is indicated by a contiguous string of markers that exhibit statistical correlation to the phenotypic trait (*see*, Specification, paragraphs [0059] and [0071]). Once a marker is found outside that contiguous string (*i.e.*, one that has a LOD-score below a certain threshold, indicating that the marker is so remote that recombination in the region between that marker and the QTL occurs so frequently that the presence of the marker does not correlate in a statistically significant manner to the presence of the phenotype), the boundaries of the QTL are set. Thus, those of skill in art may indicate the location of the QTL by naming those genetic markers that statistically correlated to the phenotypic trait located within that specified genomic region.

It is further important to note that the contiguous genomic markers can also be used to indicate the presence of the QTL (and thus of the phenotype) in an individual animal, *i.e.,* they can be used in marker assisted selection (MAS) procedures. (Specification, paragraph [0043]). In principle, the number of potentially useful markers is limited but may be very large, and the skilled person may easily identify additional markers to those mentioned in the present application without undue experimentation. Any marker that is linked to the QTL, *e.g.*, falling within the physically boundaries of the genomic region spanned by the markers having established LOD scores above a certain threshold thereby indicating that no or very little recombination between the marker and the QTL occurs in crosses; as well as any marker in linkage disequilibrium to the QTL; as well as markers that represent the actual causal mutations within the QTL, may be used in MAS procedures. *Id.* As such, the instructions and working examples in the instant specification for selecting a pig with a parentally imprinted QTL associated with muscle mass and/or fat deposition are generally applicable to other animals and

enable one of skill in the art to select other animals with parentally imprinted QTLs associated with the desired phenotype.

Specifically, the specification discloses that a phenotype for the muscle mass and/or fat deposition in a pig is linked to a parentally imprinted QTL (*e.g.*, at chromosome 2, specifically 2p1.7). The specification further discloses associating the phenotypic trait with the parentally imprinted QTL and mapping the QTL to chromosome 2 in the pig. (Specification, paragraph [0026]; Example 1, paragraph [0060]). The specification also discloses a nucleic acid sample obtained from the pig and tested for the presence of the paternally imprinted QTL on chromosome 2 of the pig. (*see*, *Id.* paragraph [0037]). When the parentally imprinted quantitative trait locus is present in the nucleic acid sample, the animal is selected as having the desired trait.

Thus, when independent claims 1 and 39 are read in light of the specification, one of skill in the art would be able to select an animal having the desired phenotypic property by testing the animal for the presence of a paternally imprinted QTL identified according to the guidelines in the specification. Arguably, it would take some experimentation to locate the parentally imprinted QTL in a candidate animal. However, following the reasoning in *In re Wands*, a considerable amount of experimentation is appropriate especially considering the nature of this technology, the high level of skill in the art and the significant guidance provided by the specification. *In re Wands*, 858 F.2d at 737. Accordingly, one of ordinary skill in the art would be able to make and use the instant invention without undue experimentation.

Reconsideration and withdrawal of the enablement rejection of claims 1-9 and 36, 39 and 40 is requested.

Entry of Amendments

Independent claim 41 is added according to the Examiners suggestions and includes elements of claim 3 including selecting a pig with a parentally imprinted QTL on chromosome 2. Claim 41 also incorporates elements of cancelled claim 5 including muscle mass and/or fat deposition in a pig. Moreover, claim 41 includes elements from claim 8 including a paternally imprinted QTL. Additionally, claim 41 recites elements from claim 36 including genetic markers linked to the QTL, genetic markers in linkage disequilibrium with the QTL, genetic markers that

represent the actual causal mutation(s) affecting muscle mass and/or fat deposition in the pig within the QTL and genetic markers Swr2516, Swc9, S22623 and Swr783 on chromosome 2 of the pig. Further support for claim 41, and those dependent therefrom, may be found in the Specification, paragraph [0026], and in Figure 3A.

Regarding claim 42, support is provided by the written description wherein it states "[t]he invention provides testing such a sample for the presence of [a] nucleic acid wherein a QTL or allele associated therewith is associated with the phenomenon of parental imprinting." (Specification, paragraphs [0010] and [0026]; Example 1, paragraph [0060])).

Regarding claim 43, support is found in the specification which describes "[i]n pigs, said cluster is mapped at around position 2p1.7 of chromosome 2." (*Id.* at paragraph [0030]).

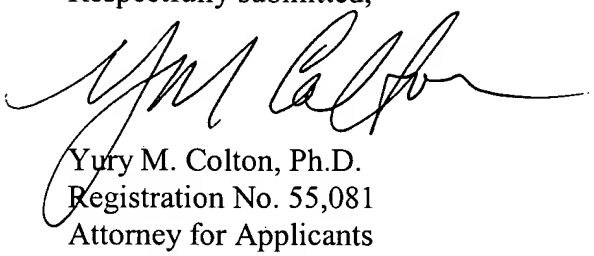
Written description support for claim 44 may be found in the specification which indicates that the "QTL is related to the potential muscle mass and/or fat deposition ... wherein said QTL comprises at least a part of an insulin-like growth factor-2." (*Id.* at paragraph [0030]).

And finally, claim 45 is supported by the specification which indicates that "a nt241 (G-A) transversion [is] in the second exon of the porcine IGFII gene and SW9." (*Id.* at paragraph [0041]).

CONCLUSION

In view of the foregoing amendments and remarks, the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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